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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/819,813	03/29/2001	John Kendrup	003300-763	1138
7590	12/02/2003		EXAMINER	
Benton S. Duffett, Jr. BURNS, DOANE, SWECKER & MATHIS, L.L.P. P.O. Box 1404 Alexandria, VA 22313-1404			PULLIAM, AMY E	
			ART UNIT	PAPER NUMBER
			1615	
DATE MAILED: 12/02/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/819,813	KENDRUP ET AL.
Examiner	Art Unit	
Amy E Pulliam	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 04 September 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-22 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-22 and 25 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Request for Continued Examination, received by the Office September 4, 2003.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-22, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,639,476 to Oshlack *et al.*.

Applicant is claiming a method for producing a controlled release pharmaceutical preparation comprising preparing a drug containing core, suspending a pore forming agent in an aqueous dispersion of a film forming polymer, coating the solid core with the suspension, and drying the coated substrate.

Oshlack *et al.* disclose a controlled release dosage form, comprising a substrate containing an active agent, said substrate being coated with a plasticized aqueous dispersion consisting essentially of copolymers which are copolymers of acrylic acid and methacrylic acid esters, and a further material which can be a pore-former. Oshlack *et al.* further teach that the coating is applied to the substrate, and the coated substrate is cured at a temperature greater than the glass transition temperature of the aqueous dispersion of said plasticizer water-insoluble

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polymer. See column 36, claim 1. Furthermore, Oshlack *et al.* teach that the controlled release coatings are aqueous dispersions of hydrophobic acrylic polymers. See column 7, lines 35-38. Oshlack *et al.* also teach that the monomers to be used in the polymer coatings may include vinyl esters, such as vinyl acetate and vinyl chloride. See column 7, lines 50-53. Also, the pore former can be selected from a large group, including alkali metal salts, such as potassium chloride. See column 10, line 45 – column 11, line 42. The active agent can be selected from a large list of actives. See column 16, line 42 – column 17, line 44.

Oshlack *et al.* is described above as teachings applicant's claimed process. Oshlack *et al.* does not specifically teach the claimed particle size for the pore formers. However, it is the position of the examiner that the determination of a particular particle size is within the skill of the ordinary worker as part of the process of normal optimization, and therefore, does not render patentable weight to the claims.

Additionally, Oshlack *et al.* does not specifically teach each of applicant's listed pore formers. However, Oshlack *et al.* does teach the use of pore formers, in general, to create a controlled release composition. Furthermore, it is the position of the examiner that one of ordinary skill in the art would have been motivated to use any pore former in the process taught by Oshlack *et al.*, because Oshlack *et al.* teaches the inclusion of pore formers, in general. The expected result would be a controlled release formulation, where the pore formers act to create channels and pores that fill with the environmental fluid. See column 10, lines 40-44. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments have been fully considered but are not found to be persuasive.

Applicants refer to the declaration for arguments regarding the rejection under 35 USC 102.

Applicants again argue that the pore formers of Oshlack do not have the required "balanced solubility" as required by the instant claims.

Initially, the examiner points out that none of the composition claims refer to balanced solubility, or to a particular solubility. Therefore, these arguments are considered moot with respect to the composition claims, claims 17-22 and 25.

Applicants argue that Oshlack teaches a wide variety of substances which have many kinds of solubilities. Applicant asserts that except for one of the pore formers listed (lithium carbonate), all of Oshlack's pore formers have solubilities which are either too high or too low for use in Applicant's composition. The examiner is not persuaded by this argument for several reasons. First, Applicant's have provided no evidence to support the assertion that only one of the pore formers taught by Oshlack has an appropriate solubility. Second, claim 1 requires a balanced solubility below 50 mg/ml. This limitation has an upper limit, but no lower limit. However, Applicant asserts that some of the pore formers taught by Oshlack have a solubility which is too low. It is unclear to the examiner how any solubility can be "too low" when there is no lower limit set forth in the claim. Third, Applicant admits that lithium carbonate has a suitability solubility (paragraph 16 of the Declaration). Therefore, Oshlack does teach a pore former with the required solubility. Applicant further argues that a skilled artisan would not consider using lithium carbonate as a pore former, because it is a potent pharmaceutical ingredient, and pore formers should be pharmaceutical excipients, not pharmacologically active

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agents. Again, Applicant has provided no support for this statement. The examiner disagrees, as Oshlack, clearly a skilled artisan in the field, teaches that lithium carbonate is a successful pore former. Absent evidence to rebut this statement, the examiner finds Applicant's arguments unpersuasive, based on the teachings of Oshlack.

Additionally, the examiner restates a portion of the arguments set forth in the last office action. It is the position of the examiner that many of the pore formers disclosed by Oshlack are, in fact, not very soluble in water, therefore falling within the limitations of Applicant's claims. For example, lithium carbonate has a solubility of 1 g / 78 mL, which equates to 12.82 mg/ 1 mL water. Additionally, starch is practically insoluble in water. Also, polyvinyl chloride is insoluble in water. (see Merck, numbers 5552, 89524, 7746). The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Applicant also argues that Oshlack *et al.* teach organic solvents, rather than aqueous. The examiner respectfully disagrees and points again to column 7, lines 35-38, where the reference teaches that the controlled release coatings are aqueous dispersions of hydrophobic acrylic polymers.

Applicant has additionally provided data and discussion of said data, in an attempt to distinguish Oshlack from the claimed invention. Table I is relied upon by Applicant to show the importance of the presence of a pore former, and the particular particle size employed. However, these experiments do not differentiate the claimed invention from the cited art. First, Oshlack recognizes the importance of a pore former. Second, Applicant has shown a difference in release rate between a 8 micron and a 14 micron particle. The examiner recognizes that there is a distinct difference in the results. However, this is not persuasive, because both the 8 and 14 micron particle fall within Applicant's claimed range, and therefore the change in results can not be a factor, as Applicant allows for both of these sizes in the claims. Furthermore, Applicant claims a very large range of particles sizes, 0.5 to 100 microns. The examiner maintains her statement that one skilled in the art would have been motivated to manipulate the particular size as part of the process of normal optimization.

Table II was to show differences in formulations using pore formers without a balanced solubility and pore formers with a balanced solubility. However, the examiner is not persuaded by this data because it is not commensurate in scope with the instant claims. Applicant relies on only one pore former, potassium hydrogen tartrate, while Applicant claims a vast number of pore formers. Additionally, Applicant's data refers to only three other pore formers. Lastly, as discussed above, lithium carbonate, which is taught by Oshlack, has a suitable solubility, based on Applicant's requirements. Therefore, all of this data is unpersuasive because Oshlack teaches an appropriate pore former.

Applicant also argues that Oshlack *et al.* teach organic solvents, rather than aqueous. The examiner respectfully disagrees and points again to column 7, lines 35-38, where the reference

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teaches that the controlled release coatings are aqueous dispersions of hydrophobic acrylic polymers.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. Pulliam
Patent Examiner
Art Unit 1615
November 28, 2003

THURMAN K PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600